Remarks/Arguments

A. Status of the Specification

The priority data in the specification is revised per the Examiner's request. Applicant requests that the objection to the specification be withdrawn.

B. Status of the Claims/Claim Objections/Indefinitness Rejections

Claim 1 is revised to remove a limitation in claim 1, while claim 11 is revised to include this limitation. Non-limiting support for this amendment can be found in the summary of the invention section of the specification and in the claims as originally filed.

Claim 7 is revised to clarify that the one or more keratinocytes and fibroblasts naturally secret one or more of the biologically active molecules listed in claim 1. This addresses the objection to claim 7.

Claims 8-10 are cancelled.

Claim 12 is revised to remove the "optionally" language.

Claims 13, 26, and 38 are revised to include a period "." at the end of the claim and to further clarify the cryoprotectant solution per the Examiner's request. Non-limiting support for this amendment can be found on page 7, lines 28-30.

Claim 21 is revised to remove "high barrier performance." Applicant notes that this phrase is clear to a person having ordinary skill in the art. A simple search on the internet would confirm this. However, in an effort to place the application in a condition for allowance, the phrase is removed. As a consequence, claim 21 is now broader in scope.

Claim 38 is revised to include a period "." at the end of the claim.

In view of the above, claims 1-7 and 11-41 are pending.

C. Double Patent Rejection

Applicant is filing a Terminal Disclaimer for U.S. Patent 7,144,729. Applicant requests that the non-statutory double patenting rejection be withdrawn.

D. Enablement Rejection

Dependent claims 8-10 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement.

Applicant respectfully disagrees with this rejection. Although some experimentation may be required to practice the subject matter of claims 8-10, the amount of experimentation is not undue; indeed modifying secretion levels of biologically active molecules in cells was well known as of the filing date of this application. *See, e.g.,* U.S. Patent 5,639,275 (disclosing methods for genetically engineering cells to modify gene expression). The art available to a person of ordinary skill in the art at the time of filing this application is sufficient to practice claims 8-10 without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (in finding the claims to be enabled, the Court stated "[t]he determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art."); *see also* MPEP § 2164.05(b) ("The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.").

However, in an effort to further the prosecution of this case and secure prompt allowance, Applicant has cancelled dependent claims 8-10. Therefore, Applicant requests that the enablement rejection be withdrawn.

E. Anticipation Rejection

Claims 1, 2, 4, 7, 11, 15, 22, 24, 28-30, 31, 33, 39, and 42 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent 6,479,052 (Marshall *et al.*). Action at page 9. In order to maintain this anticipation rejection, every element of Applicant's claimed invention must be "identically shown" in Marshall *et al.* *See In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990) ("For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.").

Claim 1 now concerns mitotically inactivated allogeneic keratinocytes or fibroblasts. By comparison, the cited art discloses "a method of adhering cells to a target surface," where the cells used appear to be mitotically active cells:

> Applicants have now shown that keratinocytes sprayed onto a wound site at about the same time frame as the spraying and mixing of two-component fibrin polymer forming systems onto the wound is effective to secure keratinocytes (and, in some cases, fibroblasts) to the wound within a three dimensional fibrin polymer matrix, where the amount of secured cells is effective to expand to form an epithelial layer. In preferred aspects of their invention, the keratinocytes are sprayed concurrently with the spraying and in-flight mixing of a two-component system that renders the fibrin-related molecules of the mixture dynamically competent to polymerize.

Id. at col. 2, line 8-18 (underline added).

Therefore the claims are not anticipated by Marshall *et al.*

In addition to not being anticipated, Applicant notes that this reference does not render the claims obvious for several reasons. For instance, there does not appear to be any apparent reason to use Applicant's claimed "mitotically inactive allogenic cells." Further, there is no reasonable expectation of success found in Marshall *et al.* that the use of such cells would work. This is especially true given that the data in this reference appears to have been obtained by

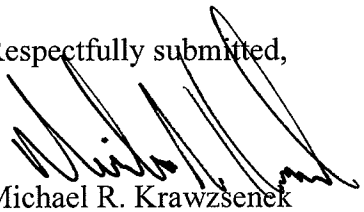
using mitotically active autologous cells. *See*, *e.g.*, *id.* at col. 12, lines 35-37 (noting that "[a] skin biopsy to initiate keratinocyte cultures was performed on the same day as the creation of full thickness wounds (isolated by percutaneous chambers) and grafted with Integra™ dermal replacement onto the thoracic trunk fascia"); *see also* col. 11, line 14, to col. 12, line 5.

Applicant requests that the anticipation rejection be withdrawn for at least the above reasons.

F. Conclusion

Applicant believes that this is a full and complete response to the Office Action mailed January 8, 2008. A Notice of Allowance is requested. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact Applicant's representative at (512) 536-3020.

Respectfully submitted,



Michael R. Krawzsenek
Reg. No. 51,898
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3020 (voice)
512.536.4598 (fax)

Date: May 5, 2008